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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,785	12/20/2000	William J. Curatolo	PC10755AJTJ	8464

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/742,785	CURATOLO ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/4/04 & 05/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-15,18-44,47-72,75-92,95-102,104-112,115-122,124-132 and 135-155.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-11,19-24,32-40,48-53,60-68,76-81,88-91,96-101,108-111,116-121,128-131,136-141 and 148-150.

Continuation of Disposition of Claims: Claims rejected are 1,2,12-15,18,25-31,41-44,47,54-59,69-72,75,82-87,92,102,104-107,112,115,122,124-127,132,135,142-147 and 151-163.

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 03/04/04; request for extension of time, IDS, amendment and remarks filed 05/19/04. Claims 1-15, 18-44, 47-72, 75-92, 95-102, 104-112, 115-122, 124-132 and 135-155 and new claims 156-163 are pending. Claims 3-11, 19-24, 32-40, 48-53, 60-68, 76-81, 88-91, 96-101, 108-111, 116-121, 128-131, 136-141 and 148-150 remain withdrawn.

Specification

The objection to the specification regarding the missing information, on page 3, line 20, will continue to be made and applicants have the option to amend the specification to correct the statement in context and in agreement with the present state of the application. It may be sufficient to refer to the PCT application now and refer to any patents issuing from the PCT application if the same becomes necessary when the current application is passed to issue; a correction is respectfully required until such a time. Applicants' statement regarding the missing item on page 3, line 20 is noted and the objection is maintained.

Claim Rejections - 35 USC § 112

1. Claims 146, 147 and 151-155 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Applicants traverse the above rejection because applicants say that "those skilled in the art know what a solution is"

2. Applicants' arguments filed 0519/04 have been fully considered but they are not persuasive.

The issue is not what a solution is or is not as applicants traverse. The issue with claims 146 and 155 is that it is not clear how the aqueous solution is formed in a use environment such as in vitro and in vivo.

3. The rejection of claims 103, 104, 123 and 124 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because claims 103 and 123 are cancelled.

Claim Rejections - 35 USC § 102

4. Claims 1, 2, 12-15, 18, 25-31, 41-44, 47, 54-59, 69-72, 75, 82-87, 92, 95, 102, 104-107, 112, 115, 122, 124-127, 132, 135 and 142-145 remain rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 5,496,561). Claims 104 and 124 are included in this rejection because of the current amendment where claims 104 and 124 depend form claims 86 and 106 respectfully.

Applicants argue that Okada does not disclose a "composition comprising a drug in a solubility-improved form and a cellulosic polymer" and does not disclose "a polymer that is member of the group required by all of Applicants' claims." Applicants state that Okada discloses corn starch use in the composition and does not disclose drugs other that the free form of the drugs as described in examples 7 and 9. Applicants concluded by stating that because Okada does not disclose a composition comprising a solubility-improved form of a drug and one of the cellulosic ionizable polymers required by applicants, Okada does not disclose the elements of Applicants' claims and Okada thus not therefore anticipate the claims and the rejection should be withdrawn.

5. Applicants' arguments filed 05/19/04 have been fully considered but they are not persuasive.

To begin with, the rejection is maintained as described in the previous office action. A solubility-improved form is according to applicants' specification is that "the term "solubility-improved form" as employed herein refers to a form of the drug which has increased solubility relative to the least soluble form of the drug known. Thus, the term implies that a less soluble form of the drug exists and is either known or has been determined, i.e., known, for example, from the scientific or patent literature, or determined by or otherwise known to the investigator. A "solubility-improved form" may consist of a highly soluble form of the drug alone, may be a composition comprising a highly soluble form of the drug plus inert excipients, or may be a composition comprising the drug in a poorly or highly soluble form and one or more excipients which have the effect of increasing the solubility of the drug, regardless of the length of time for which the solubility is increased. Examples of "solubility-improved forms" include but are not limited to: (1) a crystalline highly soluble form of the drug such as a salt; (2) a high-energy crystalline form of the drug; (3) a hydrate or solvate crystalline form of a drug; (4) an amorphous form of a drug (for a drug that may exist as either amorphous or crystalline); (5) a mixture of the drug (amorphous or crystalline) and a solubilizing agent; or (6) a solution of the drug dissolved in an aqueous or organic liquid." "Alternatively, the term "solubility-improved form" refers to a form of the drug alone or in a composition as is described above that, when delivered to an in vivo environment of use (such as, for example, the gastrointestinal tract of a mammal) or a physiologically relevant in vitro solution (such as phosphate buffered saline or a Model Fasted Duodenal solution described below) provides, or is capable of providing, at least temporarily, a

concentration of drug that is at least 1.25-fold the equilibrium concentration of drug in the use environment. (As used here, the term "equilibrium concentration" is defined below.)" " A solubility-improved form of a drug is one that meets at least one of the above definitions."

Applicant in the remarks confirmed that at least example 7 discloses a salt of a drug and the salt of a drug is more soluble that the basic drug and that form of a drug will read on the solubility-improved form. Okada discloses pharmaceutical composition comprising crystalline form of a drug (column 3, line 32); polymer such as hydroxypropylmethylcellulose acetate succinate, hydoxypropylmethylcellulose phthalate, cellulose acetate phthalate and carboxymethylethyl cellulose (column 3, lines 36-39, column 4, lines 20-25); plasticizers such as triethyl citrate, triacetin, polyethylene glycol, castor oil, polysorbitan monooleate, glycerine fatty acid ester (column 5, lines 5-8); hydroxypropylmethylcellulose acetate succinate, hydoxypropylmethylcellulose phthalate, and cellulose acetate phthalate are some of the polymers now recited by amendment in claim 1. Therefore, Okada discloses some of the polymers recited in the amended claims and thus meets that limitation. Okada discloses every limitation of the designated claims.

Okada administers the composition comprising active agent and polymers such as hydroxypropylmethylcellulose acetate succinate, hydoxypropylmethylcellulose phthalate, cellulose acetate phthalate and carboxymethylethyl cellulose (column 3, lines 36-39, column 4, lines 20-25 column 5, lines 55-61). Administration at essentially the same time reads on administering the drug and the polymer at the same time. Essentially the same time is essentially at the same time.

6. The rejection of claims 1, 2, 12-14, 25-31, 41-43, 54-59, 69-71, 82-87, 102, 105-107, 122, 125-127, 133 and 142-145 under 35 U.S.C. 102(b) as being anticipated by Piergiorgio et al. (US 4,880,623) is not maintained Piergiorgio does not disclose any of the polymers now recited in the amended generic claims. Applicants' argument with respect to Piergiorgio is persuasive.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 30, 58, 106, 126, 146 and 155-163 are rejected under 35 U.S.C. 102(e) as being anticipated by Curatolo et al. (US 6,548,555).

Curatolo discloses a composition that comprises cellulose polymer selected from hydroxypropylmethylcellulose acetate succinate (HPMCAS), cellulose acetate trimellitate (CAT), cellulose acetate phthalate (CAP), hydroxypropylcellulose acetate phthalate (HPCAP), hydroxypropylmethylcellulose acetate phthalate (HPMCAP), and methylcellulose acetate phthalate (MCAP) and basic drug, zewitterionic drug or the salt of the drug (abstract); an example of basic drug delivered by the composition is ziprasidone (column 7, line 4); the basic drug is delivered to a use environment with the polymers listed above (abstract); or the drug and the polymer are administered to the use environment as a composition (column 6, lines 27-33). Once the tablet form is administered, it would inherently form aqueous solution in the use environment, in this case, the GI tract.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

8. Claims 1, 30, 58, 106, 126, 146 and 155-163 are rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al. (US 2003/0215496).

Patel discloses pharmaceutical composition that comprises solid carrier, surfactants, additives and drugs (abstract), one of the drugs that is deliverable with the carrier composition is ziprasidone (paragraph [0038]); cellulose acetate trimellitate, hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose succinate and cellulose acetate phthalate additives (paragraph [0185]) are included in the composition. Patel's compositions can be provided in the form of a minicapsule, a capsule, a tablet, an implant, a troche, a lozenge (minitablet), a temporary or permanent suspension, an ovule, a suppository, a wafer, a chewable tablet, a quick or fast dissolving tablet, an effervescent tablet, a buccal or sublingual solid, a granule, a film, a sprinkle, a pellet, a bead, a pill, a powder, a triturate, a platelet, a strip or a sachet; and Patel's compositions can also be administered as a "dry syrup," where the finished dosage form is placed directly on the tongue and swallowed or followed with a drink or beverage (paragraph [0168]). Once these dosage forms are administered, the composition would inherently form aqueous solution in the use environment, in this case, the GI tract.

Claim Rejections - 35 USC § 103

9. The rejection of claims 15, 18, 44, 47, 72, 75, 92, 95, 112, 115, 132 and 135 under 35 U.S.C. 103(a) as being unpatentable over Piergiorgio et al. (US 4,880,623) is withdrawn because

the amendment to the generic claims where specific polymers are recited removes Piergiorgio as prior art since Piergiorgio does not disclose the polymers now recited in the amended claims. Applicants' argument is persuasive.

Double Patenting

The provisional rejection of claims 1, 18, 25-28 and 30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3. 6, 7, 10 and 12-14 of copending Application No. 10/176,462 is withdrawn because applicants' argument that the instant claims do not teach/recite the drug forms (nanoparticulate form, absorbed form, nanosuspension, supercooled melt, cyclodextrin/drug form, gelatin form, softgel form, self-emulsifying form and three-phase drug form) taught in the issued claims is persuasive.

Observation: Examiner acknowledges applicants' objection to the observation and suggestion to change cellulosic to cellulose. Examiner's observation is not maintained.

10. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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